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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,244	06/27/2001	Barry S. Fogel	0264724-0031	4907

20995 7590 01/30/2007

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EXAMINER	
WILLIAMS, LEONARD M	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	01/30/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/30/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No.	Applicant(s)	
	09/893,244	FOGEL, BARRY S.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *31 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *85-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *85-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/8/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2006 has been entered.

Response to Amendments/Arguments

Applicant's amendment to the claims cancelling claims 81-83, 89 and 90 has been entered. Claims 85-88 are currently pending. No additional amendments were made.

Applicant's arguments filed 10/31/2006 have been fully considered but they are not persuasive. The applicant's have filed a 1.132 declaration in support of their assertion that the combination of acamprosate and magnesium has synergistic effects and thus the combination has unexpected results. On page 2 of the declaration it is asserted that the patient in case report 5 of the present application (46 year old man) was previously treated with magnesium oxide (equivalent to 250mg elemental magnesium) three times a day for several days with no improvement of the patients

symptoms. The declaration goes on to describe that the patient was then treated with acamprosate alone three times a day with reduced frequency and duration of the patients symptoms. Further when chelated magnesium oxide was added three times a day in addition to the acamprosate (equivalent to 300mg elemental magnesium) the usual tic-free period after each acamprosate dose increased from 3 to about 5 hours. The examiner respectfully points out that this does not demonstrate synergism of the two compounds. The dosage of magnesium given with the acamprosate concurrently is higher than the dose given when magnesium was administered alone. Further the declaration says that when magnesium was given alone it was in the form of magnesium oxide, when it was given in combination with acamprosate it was in the form of chelated magnesium oxide. It is known that chelated minerals are more readily absorbed in the digestive track than non-chelated forms. For these reasons and the reasons of record the declaration is deemed insufficient to overcome the rejections of the previous office action.

The rejections of the previous office action have been modified to address only the currently pending claims (removal of the canceled claims from the rejection). The rejections are detailed below.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 85-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidsky (US Patent No. 5602150), in view of Vetulani (Review Drug Addiction. Part III. Pharmacotherapy of Addiction, Polish Journal of Pharmacology, 2001, Vol. 53, pp. 415-434), in view of Bormann et al. (US Patent No. 5061703) and further in view of Decollogne et al. (NMDA Receptor Complex Blockade by Oral Administration of Magnesium: Comparison with MK-801, 1997, Pharmacology Biochemistry and Behavior, Vol. 58, No. 1, pp. 261-268).

Lidsky et al. teach in, the abstract and col. 10 lines 35-65, a method of treatment and a composition to prevent the development of the adverse manifestation of tardive dyskinesia in patients undergoing treatment with a neuroleptic or antipsychotic agent comprising administering the neuroleptic or antipsychotic agent with taurine, a taurine precursor, taurine derivative, or compounds similar in action to taurine including acamprosate (as evidenced by applicant's own admission, see current specification page 23, line 25).

Lidsky does not teach that acamprosate is to be administered with a second active moiety comprising an NMDA-type glutamate antagonist, nor exactly by what mechanism acamprosate and the other taurine derivatives work.

Vetulani teaches, on page 424, that acamprosate acts as both a GABAergic neurotransmitter enhancer and as an antagonist of glutamatergic neurotransmission via the NMDA receptor. Thus acamprosate is both a GABA agonist and a NMDA antagonist.

Decollogne et al. teach, in the abstract and on page 265, that oral treatment with a single dose of magnesium organic salts (such as magnesium aspartate, magnesium lactate) leads to an increase in serum Mg2+ concentration and that magnesium is a noncompetitive ion-channel blocker of the NMDA receptor complex.

It would have been obvious to one of ordinary skill in the art at the time of the invention was made that acamprosate (a GABA agonist and NMDA-receptor antagonist and magnesium (an NMDA-receptor antagonist) targeted the same receptor pathways. Additionally Lidsky demonstrated that acamprosate was effective in the prevention of tardive dyskinesia associated with neuroleptic and antipsychotic drugs. One of ordinary skill would know that compounds targeting the same receptor have similar activities and could be used in the treatment of similar conditions.

The examiner respectfully points out the following from MPEP 2144.06:
"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER